

The Contribution of International Organizations, in Particular of the European Union, to the Fight against Global Health Threats: COVID-19 and its Challenges and Opportunities

La Contribución de las Organizaciones Internacionales, en particular de la Unión Europea, a la lucha contra las amenazas globales a la salud: la COVID-19 y sus desafíos y oportunidades

Francesca Delfino¹

LUISS Guido Carli University, Roma (Italia)

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Abstract

The protection of health, initially implemented in terms of charity, in favour of the poor and the destitute and by specific public and private bodies, with the conclusion of numerous international treaties becomes a fundamental human right that no longer falls within the exclusive competence of the State alone. The value and crucial role of the right to health have been recently rediscovered during the health emergency caused by the COVID-19 pandemic. Unfortunately, the outbreak of the serious health crisis found the international community and the European Union unprepared to give an unequivocal and coordinated response

¹ (fdelfino@luiss.it). Francesca Delfino is currently an assistant professor and a tutor at the Department of Law within the University Luiss Guido Carli from Rome. In 2010, she got a Law degree in European Law at the University LUISS Guido Carli and in 2015, a PhD degree in International Law from the University "G. D'Annunzio" (Chieti – Pescara, Italy). She is also a lawyer and author of many publications in the field of International law and European Union law. Her most recent publication is " 'Consideration of humanity' in the Jurisprudence of ITLOS and UNCLOS Arbitral Tribunals" a chapter contributed to "Interpretations of the United Nations Convention on the Law of the Sea by International Courts and Tribunals", published in 2019.

ORCID: <https://orcid.org/0000-0001-7525-1195>

to guarantee the protection of this fundamental right. The article undertakes a critical analysis of the contribution made so far to tackling the global threat posed by COVID-19, on the one hand, by the WHO, the main international organization dealing with global health and, on the other hand, by the European Union, a regional integration organization to which States have not attributed competences in health matters.

Key-words: Right to health, World Health Organization, European Union, COVID-19, Pandemic, Solidarity, Coordination.

Resumen

La protección de la salud, implementada inicialmente en términos de caridad a favor de los pobres y los desamparados por organismos públicos y privados específicos, con la estipulación de numerosos tratados internacionales se convierte en un derecho humano fundamental que ya no es de la competencia exclusiva del Estado. El valor y el papel crucial del derecho a la salud se han redescubierto recientemente durante la emergencia sanitaria provocada por la pandemia de COVID-19. Lamentablemente, el estallido de la grave crisis sanitaria encontró a la comunidad internacional y a la Unión Europea poco preparadas para dar una respuesta unívoca y coordinada que garantizara la protección de ese derecho fundamental. El presente artículo lleva a cabo un análisis crítico de la contribución realizada hasta el momento en el desafío de afrontar la amenaza global que plantea la COVID-19; de un lado, por la OMS, principal organismo internacional que se ocupa de la salud global, y, de otro, por la Unión Europea, organización de integración regional a la que los Estados no han atribuido competencias en materia de salud.

Palabras-clave: Derecho a la salud, Organización Mundial de la Salud, Unión Europea, COVID-19, Pandemia; Solidaridad, Coordinación.

1. A general overview

In the legal world, health protection was originally understood mainly from the point of view of public intervention, in order to prevent and treat epidemic or contagious diseases, thereby applying unilateral quarantine measures in such cases. Conversely, when it came to general practice, it used to be implemented in terms of charity, in favour of the poor and destitute, also within the framework of a very broad discretionary power on the part of specific public and private bodies². Therefore, public authorities were only concerned

² Piero Alberto Capotosti, "I limiti costituzionali all'organizzazione e al funzionamento del S.S.N.

with the state of health of individuals where the spread of disease could pose a collective danger. Thus, the main concern of States was to protect themselves from the epidemic or pandemic spread of serious infectious diseases and to protect freedom of trade.

Moreover, the protection of health was not initially considered as an individual right but was the domain of charity, goodwill, pious works and hospital orders, an act of liberality towards “the lowest of the low”. As a person, the individual could not demand help from the community in the event of a health need, nor was there an obligation on the part of the State to provide such a service³.

The distinction between the purely charitable dimension and positive law can only be traced back to 1748. In that year, Montesquieu, in his work *L'esprit des lois*, stated: “A few coins given to a naked man in the streets is not enough to fulfil the obligations of the State, which owes to all citizens a livelihood, food, decent clothing and a kind of life that is not harmful to their health”⁴. Thus, a first definition was also given of what the current social determinants of health are, namely those factors that influence the state of health of an individual and – more extensively – of a community or population.

Health determinants can be grouped into various categories: personal behaviours and lifestyles; social factors that can prove to be an advantage or disadvantage; living and working conditions; access to health services; general socio-economic, cultural and environmental conditions; genetic factors. Therefore, at the beginning of the 19th century, there was already an awareness that people’s health was also influenced by social as well as biological factors.

From this, it follows that the theme of health is very broad and relevant both to the individual and to the community as a whole. However, initially, in the absence of international standards, the intervention of States was exclusive in an area such as health, where the choices made are very important and the identification of priorities is decisive. Hence, health issues fell within the domain reserved to the State, which since ancient times was free to control its borders in order to safeguard national public health, limit the movement of people and goods in order to combat the spread of infectious diseases and freely decide to organise and manage its public health system.

In more recent times, health protection has found its way into the constitutions of individual States. Witness the “diritto alla salute” of Article 32 of the Italian Constitution, the “droit à la santé” of the French system, the “direito à protecção da saúde” of Article 64(3) of the Portuguese Constitution or

nella giurisprudenza della Corte Costituzionale”, in *Annuario Dras* 2010, R. Balduzzi (ed.), Milan, Giuffrè, 2010, pp. 315 ff.

³ Renato Balduzzi, Guido Carpani (eds.), “Manuale di diritto sanitario”, Bologna, Il Mulino, 2013, pp. 13-19.

⁴ Montesquieu, “De l'esprit des lois” (1748), *Livre XXIII, Chap. XXIX*, unofficial translation.

the “derecho a la salud” of Article 43 of the Spanish Constitution. This phrase is also widely used in Latin American countries, as can be seen, for example, in Articles 196 *et seq.* of the Brazilian Constitution.

Thus, the right to health soon no longer found an exclusive forum in the numerous national legal systems and their constitutions. Indeed, attention and sensitivity to health protection also began to manifest themselves at the international level. Above all, in the face of health emergencies, the National Health Conferences, which represent the first forms of international cooperation, began to be convened over time. The first Health Conference was held in Paris in 1851, in response to the cholera epidemics of 1830 and 1847, which killed tens of thousands of people in Europe⁵. During said Conference, the International Health Regulations of 1851 were drawn up, representing the first concrete example of international legal norms aimed at regulating maritime quarantine. Other conferences followed, and numerous bilateral and multilateral agreements were concluded with the aim of harmonising public health measures.

The protection and promotion of health, aimed at the prevention and reduction of individual and community vulnerability in the early 1860s, was also guaranteed by the foundation in Geneva of the International Committee of the Red Cross (ICRC) in the form of a non-profit, private law association under Swiss law.

The beginning of the 20th century also saw the creation of various international bodies such as the Pan American (originally International) Sanitary Bureau in Washington D.C. in 1902 – renamed Pan American Health Organization in 1956 – to improve health conditions in North and South America. In 1907, the International Office of Public Health was established in Paris, and in 1920 the League of Nations Health Organisation was founded in Geneva. Said bodies soon took on an important role in the field of public health, gradually leading to an erosion of the sovereignty of States⁶ and the institutionalisation of international cooperation.

International cooperation for the solving of international health problems was consolidated at the end of the Second World War with the San Francisco Charter, which established the United Nations (hereinafter also referred to as the UN). In particular, one of the priorities of the UN, as evidenced by Articles 55 and 62 of the San Francisco Charter, is the protection of health worldwide. This establishes a link between health protection and the maintenance of international peace and security⁷.

⁵ Makane Moïse Mbengue, “Public Health, International Cooperation”, in Max Planck Encyclopedia of Public International, Oxford, UK, Oxford University Press, 2010.

⁶ See Stefania Negri, “La salute pubblica nell’era della globalizzazione”, in *Salute pubblica, sicurezza e diritti umani nel diritto internazionale*, Turin, Giappichelli, 2018, p. 33.

⁷ For further information, see Ana Cristina Gallego Hernández, “El Derecho Internacional De La

1946 saw the establishment of the World Health Organization (hereinafter referred to as WHO), which is a specialized agency of the United Nations, on the basis of Article 57 of the UN Charter and Article 69 of the Statute of the organization itself, and is normally classified by scholarly opinion as a typical international technical organization that has replaced a variety of small international organizations, including the health branch of the League of Nations⁸.

Over the same period, at the international level, the international community has continued to include the right to health in a wide range of international and regional instruments⁹. In them, health is considered a fundamental human right¹⁰ and constitutes the highest level of physical and mental wellbeing permitted by one's physical condition.

Thus, the protection of health, which was initially implemented in terms of charity, in favour of the poor and destitute and by specific public and private bodies, becomes a fundamental human right that no longer falls within the exclusive jurisdiction of the State alone.

With quarantine measures considered insufficient, around the mid-19th-early 20th century, international cooperation was first established through bilateral and multilateral agreements. Then, around the mid-20th century, international cooperation in health matters was institutionalized. Finally, around the end of the first half of the 20th century, international health legislation was created, a process that coincided with the birth and guiding role of the WHO¹¹.

Salud A La Luz De La Paz Y Seguridad Internacionales”, Madrid, Dykinson, 2019.

⁸ It has been pointed out in literature that the birth of the WHO and the conventional introduction of health protection in the lexicon of international human rights law would have sanctioned the inadequacy of unilateral quarantine measures as instruments of defence. See Pia Acconci, “Tutela della salute e diritto internazionale”, in *Diritto Internazionale e Ordine Mondiale*, Series directed by Paolo Picone, Padua, Cedam, 2011, p. 79.

⁹ For example, the right to health is officially enshrined in the 1948 Universal Declaration of Human Rights and the contemporary American Declaration of the Rights and Duties of Man.

¹⁰ Even in literature, the right to health has been considered a human right and, in particular, a “derecho humano primordial, indivisible, interdependiente y autónomo”. In this regard, see Ana Cristina Gallejo Hernández, “El derecho a la salud en la jurisprudencia del Tribunal Europeo de Derechos Humanos y de la Corte Interamericana de Derechos Humanos”, in *Araucaria. Revista Iberoamericana de Filosofía, Política, Humanidades y Relaciones Internacionales*, 40/ 2018, pp. 631-653.

¹¹ Obijiofor Aginam, “International Law and Communicable Diseases”, *Bulletin of the World Health Organization*, 80 (12): 946 - 951. World Health Organization. 2002; Xavier Seuba Hernández, “Los orígenes de la cooperación sanitaria internacional”, in Xavier Pons Rafol (ed.), *Salud pública Mundial y derecho internacional*, Madrid-Barcelona- Buenos Aires, Marcial Pons, 2010, pp. 67-87; Brigit Toebes, “International Health Law: An Emerging Field of Public International Law”, in *Indian Journal of International Law*, 55, pp. 299–328, 2015; Stefania Negri, “Communicable disease control”, in Gian Luca Burci and Brigit Toebes (eds.), *Research Handbook on Global Health Law*, Cheltenham, UK- Northampton, MA, USA, Edward Elgar Publishing, 2018, pp. 269-270.

2. The role of the WHO and its constitutional powers in managing health emergencies.

The WHO is the primary international organization which intervenes in the protection of public health worldwide under the governance framework of the International Health Regulation (hereinafter referred to as IHR) which entered into force in 2007. The IHR is a modern instrument that requires Member States to cooperate with the WHO in good faith in order to achieve the results that the Regulation aims at. However, with respect to these obligations, there is no typical sanction mechanism or mandatory dispute resolution. Moreover, the IHR rules out the possibility of a dispute between WHO and private entities, individuals and other international organizations.

In fact, however, this mechanism has never worked. The IHR also gives the WHO a broader and more incisive investigation and action role in controlling the spread of epidemics. Witness the powers attributed by Article 12 of the Regulation to the Director-General to declare the existence of an international emergency and to inform States of the most appropriate response measures, as well as the possibility that these powers may be exercised, with the help of the Emergency Committee provided for in Article 49, even without the consent of the State concerned.

Precisely on the basis of Article 12 of the International Health Regulations, on 30 January 2020 the Director-General of the WHO, following the indications of the Emergency Committee, declared that the spread of the new coronavirus¹² “meets the criteria for a Public Health Emergency of International Concern”¹³, adopting a set of temporary recommendations addressed to the States of the International Community in order to contain the contagion. At that time, the outbreaks had not yet occurred on a large scale, as would occur a few months later. Indeed, on 11 March 2020 the Director-General stated that the spread of COVID-19 had reached pandemic levels. Pandemic means the outbreak of a disease “occurring worldwide, or over a very wide area, crossing international boundaries, and usually affecting a large number of people”¹⁴.

In these difficult circumstances, the United Nations General Assembly, in its resolution of 8 April 2020, took the opportunity to reiterate once again the key role of the United Nations system in coordinating the global response to the control and containment of the spread of the disease caused by COVID-19

¹² The new coronavirus known as “COVID-19” (the acronym stands for Coronavirus Disease-2019) is a disease characterized by a severe acute respiratory syndrome with a high level of contagiousness. It was first identified in the city of Wuhan in China in late 2019 and has spread worldwide, causing unprecedented effects on the economies of all states, trade and the circulation of people, with a devastating impact on their existence.

¹³ See WHO, Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 30 January 2020.

¹⁴ *Ibidem*.

and in supporting Member States, acknowledging the key leadership role of the WHO¹⁵.

However, the serious and extraordinary situation generated by COVID-19 has instead proved to the world the need to have a WHO – which has unfortunately shown serious limitations during the crisis – that is reformed and able to ensure adequate cooperation. As a matter of fact, the temporary measures of 30 January 2020 adopted by the Director-General of the WHO, but also the numerous recommendations and guidelines of the WHO have demonstrated their lack of effectiveness and inadequacy in ensuring the coordination of States in the fight against the pandemic. Indeed, while COVID-19 was impacting the entire globe, each government worked independently to keep their communities safe and to enable an effective response to the pandemic. This situation highlighted the need for increased coordination and information sharing beyond national boundaries to develop and implement common strategies to protect human health.

Human health depends not only to accessible health care but also on access to accurate and reliable information about the nature of the threat represented by COVID-19. Access to accurate, prompt and updated information in times of crises helps people make safe choices for themselves, their families and the whole community. The right to information is recognized under international law as fundamental human right. Consequently, States have an obligation to respect this fundamental right by providing truthful information on pandemic situations and fighting disinformation. Moreover, the absence of coordination and shared actions among States is supported by the fact that many governments, in order to address the unprecedented situation and the inability of their national systems to do so, have taken additional health measures, under Article 43 of the IHR¹⁶, often restricting the personal freedoms of their citizens¹⁷.

In fact, Article 43 of the 2005 Regulation provides the possibility of going beyond the actions recommended by the WHO, providing for the possibility of applying measures in accordance with the respective national legislation,

¹⁵ See the resolution adopted by General Assembly 74/274, *International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19*, of 20 April 2020. On the other hand, the Security Council was unable to reach an agreement on a resolution on Covid-19 due to the lack of consensus between the United States and China. Instead, in the Ebola case, the intervention of the Security Council had an innovative scope. On this last point, see Federico Casolari, *Il contributo delle organizzazioni internazionali e regionali alle gestioni delle crisi sanitarie: il caso dell'Epidemia di Ebola*, in Emanuele Cimiotta and Nicola Napolitano (eds), *Nazioni Unite e organizzazioni regionali tra autonomia e subordinazione*, Bologna, il Mulino, 2019, pp. 217-252.

¹⁶ See International Health Regulations (2005): Annual report on the implementation of the International Health Regulations (2005), Report by the Director-General, A73/14, 12 May 2020, where it is acknowledged that, as at 28 March 2020, 136 States have notified the adoption of additional health measures, in accordance with Article 43 of the IHR.

¹⁷ See Antonio J. Palma, "Pandemia e diritti umani: l'Italia e lo Stato di eccezione al tempo del Coronavirus", in *Ordine Internazionale e diritti umani*, 2020, p. 304.

especially when this choice is in favour of more effective measures than the international obligations, but only under certain conditions. However, this has led States to provide an unclear response in this health emergency. Indeed, it was the States that were responsible for identifying ways of preventing and controlling the virus within their own jurisdiction, and they gave a slow and fragmented response. There was a lack of bona fide multilateral cooperation. Unilateralism between States prevailed.

Therefore, the Regulation does not seem, in this case, to have ensured uniformity of standards in this area. The inadequacy of the WHO measures was also highlighted once again when, on 16 March 2020, EU Commission President Ursula Von der Leyen admitted that “While travel restrictions are generally not seen by the World Health Organisation as the most effective way of countering a pandemic, the rapid spread of COVID-19 makes it essential that the EU and Member States take urgent, immediate and concerted action not only to protect the public health of our populations, but also to prevent the virus from further spreading from the EU to other countries”¹⁸.

Indeed, in today’s globalized, interconnected world it is impossible to separate the individual actions of States or the European Union from international policy. Increasingly, global health issues are having an impact on national and European health policies and vice versa. As a matter of fact, the outbreak of the serious health crisis, caused by the spread of the new coronavirus, is now an important test case for assessing the response capabilities and tools available not only to the international community, but also to the European Union.

Cross-border cooperation on the prevention and control of infectious diseases is essential because nowadays diseases know no borders and an epidemic that is not fully addressed or even eradicated in one country poses a certain danger to other countries, both near and far. Viruses, which are invisible yet powerful enemies, are a constant threat to humans. As pointed out by the writer Laura Spinney, viruses are not part of history: viruses make history¹⁹. The consequences they entail, both short- and long-term, are epochal in nature. However, there is no doubt that the danger of viruses has also been exacerbated by globalization. In actual fact, globalization has increased the vulnerability of public health in all nations, and only with a coordinated and collaborative effort can we hope to address the increased health risks.

Indeed, the extreme mobility, interdependence and interconnection of today’s world create a multiplicity of conditions conducive to the rapid spread of infectious diseases and threats. The geographical spread of infectious diseases is now progressing more rapidly than at any other time in history

¹⁸ European Commission, Communication From The Commission Covid-19: Temporary Restriction On Non-Essential Travel To The Eu, COM (2020) 115 final.

¹⁹ Laura Spinney, “1918. L’influenza spagnola. La pandemia che cambiò il mondo”, Venice, Marcilio Editore, 2017 (Second digital edition, 2020).

due to the increasing circulation of people and goods and climate change. COVID-19 is the second pandemic in a globalized world in which the virus has moved rapidly from one continent to another on board aircraft, just as the H1N1 influenza virus did.

This health emergency has shed new light on the value of the right to health and the crucial role of healthcare and its workers, brutally highlighting the need, which until now had been hidden from the eyes of a distracted public, of intensive care and infectious disease wards. In my opinion, this can only lead to disruptive and innovative social and health changes at national, European and international level compared to those recorded to date, thereby accelerating the processes that were already underway. As highlighted by the High Representative for Foreign Affairs and Security Policy Josep Borrell “major crises are also trend accelerators”²⁰.

Now more than ever, it is clear that globalization has meant overcoming the concept of national public health, replacing it with that of global health and increasing internationalization of risk²¹. The data on contagion, the speed of spread of the COVID-19, and the number of countries and continents affected have made it clear that health is global.

Moreover, as authoritative literature has highlighted, due to globalization, the protection of the most important social aspects such as health has been taken away from the legal regulatory framework of individual countries, creating aggregation and homologation trends governed by “unitary governments”²².

In this context, brought about by processes of interests globalization, we are witnessing a loss of the state-centric dimension and the interference in the public health sector of a plurality of international non-State actors such as non-governmental organizations, representatives of civil society, philanthropic associations, research institutes and multinational companies (representing the private sector). Public-private partnerships are now being formed as a response to the inability and unpreparedness of the public or private sector to individually address global health issues on their own. International organizations, which instead are the expression of the public sector, now more than ever play a very important role in the field of public health, because they can direct and guide States towards coordinated actions through the adoption of multiple acts. The emergency situation of the last few months has shown that, in such cases, States must pursue the development of common actions more resolutely. In order to achieve this objective, however, the WHO must overcome the structural

²⁰ Josep Borrell, “Il mondo del dopo-Covid è già qui...”, in *Istituto Affari Internazionali Papers*, April 2020.

²¹ Stefania Negri, “La tutela della salute pubblica internazionale tra governance globale”, in *supra cit.* note 6, 2018, p. 22.

²² Angela Del Vecchio, “I tribunali internazionali tra globalizzazione e localismi”, II ed., Bari, Cacucci Editore, 2015, p. 33.

weaknesses inherent in its Constitution and regulations, which emerged during the COVID-19 emergency. These weaknesses were evidenced by the WHO's inability to ensure compliance by States with its recommendations, by the shortcomings in the WHO's approach, based more on the rule of experts than on the rule of law, by the absence of the IHR sanctioning system, which does not guarantee the effectiveness of States' obligations and by the lack of an adequate dispute settlement mechanism that facilitates peaceful resolution. It is worth emphasizing that the COVID-19 pandemic highlighted that the successful implementation of the IHR cannot merely depend on the good faith of States Parties.

Therefore, the unprecedented crisis due to the sudden escalation of the pandemic should lead to a rethinking of the WHO structure, which has proved to have more cons than pros in this situation.

3. Public health in the European regulatory landscape.

While the WHO has been the key institution in cross-border cooperation on communicable infectious diseases since its inception, the European Union, as a regional integration organization, was excluded from this role for a long period of time. Indeed, the latter began to deal with health policy and related issues relatively late. European legislation in the field of health was extended in parallel with the expansion of the European integration process.

In particular, the health policy of the Union has developed as a consequence of the free movement of people and goods in the internal market, as a phenomenon that required the coordination of public health issues. In the transition from the Maastricht Treaty to the Amsterdam Treaty first, and then to the Lisbon Treaty, the Union's competence in the field of health underwent expansive changes. The expansion of this competence was not always planned and gradual, but many events such as mad cow disease, SARS, A/H1N1 influenza, Ebola and Zika epidemics affected and highlighted the limitations in the effectiveness of State interventions, contributing to determining the need for a more incisive European action.

The last revision Treaty, the Lisbon Treaty, has endowed the European Union with a composite set of competences for the protection of health, an expression of the progressive increase in the importance of health protection in the activities of the European Union.

The main provisions are found, first of all, in Article 4(2)(k) of the Treaty on the Functioning of the European Union (hereinafter referred to as TFEU), with regard to "common safety issues in public health" as an area of shared competence. In this case, the European Union acts, according to the principle of

subsidiarity, when the action of the Member States is found to be less effective than coordinated action by the Member States or the European Union as a whole.

Article 6(a) TFEU, which identifies the Union's competence in the field of health with the so-called supporting, coordinating and supplementing powers, is of particular importance. These are the powers that the Union can exercise in parallel with the action of the Member States to make the latter's work more efficient and coordinated, but without replacing their competence in this area or leading to its progressive depletion. Therefore, the European Union cannot exercise this power for harmonization purposes, except in the cases expressly provided for in paragraph 4 of Article 168 TFEU²³ nor can it impose on Member States health protocols or binding measures for the prevention or control of diseases.

Furthermore, the Lisbon Treaty has introduced in Article 6(f) TFEU a complementary power of the European Union to take action to support, coordinate and supplement the action of Member States, among other things, in the field of civil protection.

In this sense, Article 6(f) is a primary law provision that constitutes the legal basis of the body of law that can be traced back to the so-called EU Disaster Response Law.²⁴

The EU Disaster Response Law package consists mainly of three tools.

First, on a preventive level, there is the European Civil Protection Mechanism, introduced by Decision 1313/2013/EU, which was created with the aim of promoting coordinated action by the States of the Union in case of disaster or catastrophe. According to Decision 1313/2013/EU, a disaster or catastrophe is defined as "any situation which has or may have a severe impact on people, the environment, or property, including cultural heritage"²⁵.

Secondly, on a different level, aimed at providing active intervention to stem the current crisis, Article 222(1) TFEU provides for a solidarity clause, according to which the European Union is legally obliged to support any

²³ Among acts of harmonization in health matters, which find their legal basis not only in Article 168(4) but also in Article 114, is the Directive on "cross-border patient mobility". The aim of this Directive is to ensure access to safe and high-quality cross-border healthcare in the Union and to promote patient mobility in accordance with the principles laid down in the case law of the Court of Justice and to encourage cooperation between Member States in the field of healthcare, while fully respecting Member States' powers regarding the definition of social security benefits, the organization and delivery of healthcare, medical care and social security benefits, in particular sickness benefits. See Directive 2011/ 24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patient rights in cross-border healthcare, in OJEU L 88 of 4 April 2011, p. 45 ff.

²⁴ Decision of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, Decision 1313/2013/EU OJ L 347/924, 17 December 2013.

²⁵ Article 4 of Decision No 1313/2013/EU of 17 December 2013, in OJEU L 347 of 20 December 2013, p. 924 ff., last amended by Decision No 2019/420/EU of 13 March 2019, in OJEU L 771 of 20 March 2019, p. 1 ff.

Member State that is the victim of a terrorist attack or natural or man-made disaster, should the Member State so request. Therefore, on the basis of this provision, Member States are obliged to intervene in support of the requesting Member State by taking the most appropriate measures. As specified in detail in the implementing Decision 2014/415/EU, the solidarity clause cannot be applied outside of the EU, such as the collective response must be on the territory of a Member State.

In recent times, Member States have come close to activating article 222 TFEU in two cases. However, due to the lack of its external dimension, the solidarity clause did not come into play either during the European refugee crisis of 2015/2016 or in the aftermath of the ISS crisis attacks on 13 November 2015. In the first case, while the EU Member States refrained from applying article 222 because the Balkan bottlenecks involved no EU Member States, by contrast the Commission acted promptly to address the problem. In the second case, President Hollande, after the terrorist attacks in Paris, invoked for the first time the mutual assistance clause provided by article 42(7) TEU, requesting aid and assistance from other Member States in accordance with article 51 of the United Nation Charter.

Indeed, article 42(7) TEU provides that if an EU State is the victim of armed aggression on its territory, the other EU Member States have an obligation to aid and assist it by all the means in their power. The precise identification of the most appropriate means to fulfil this obligation remains entrusted to the single State. Contrary to article 222 TFEU, the European Union is not taken into consideration in the regulatory provisions of article 42(7) TEU. The addressees of the aid and assistance obligation are only Member States; and the Union is not even assigned the task of coordinating the interventions of Member States. The reason for the unsuccessful application of article 222 TFEU can be identified in its essentially internal dimension. It guarantees assistance to the victim State on its own territory, while France also asked for help from outside.

To date, the provision has never been invoked by a Member State. However, even in the absence of a legal obligation in this sense, during the COVID-19 emergency there have been many gestures of solidarity within the European Union: for instance, the German Länder have made their intensive care facilities available to seriously ill patients from Italy, France and the Netherlands, and the European Commission has also handed over 1.5 million masks to 17 Member States and the United Kingdom in order to protect health workers²⁶.

²⁶ With regard to solidarity initiatives between Member States, please refer to “Coronavirus: European solidarity in action” (available online: https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/coronavirus-european-solidarity-action_ithttps://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/coronavirus-european-solidarity-action_it).

Finally, Decision 1082/2013/EU²⁷, which repealed and replaced Decision 2119/98/EC²⁸, strengthens the rules on serious cross-border threats to health, epidemiological surveillance, monitoring, early warning and combating serious cross-border threats to health, including preparedness and response planning in relation to these activities, in order to improve the coordination of the supranational response, which is entrusted to the Health Security Committee, a group of experts composed of representatives of the Member States.

Moreover, Article 11(4) of Decision 1082/2013/EU provides that, in the event of a serious cross-border health threat for which national response capacities are insufficient, the Member State concerned may request assistance from other EU countries through the European Civil Protection Mechanism.

Article 6 TFEU finds in turn its fullest expression in Article 168 TFEU, which opens Title XIV of Part III of the Lisbon Treaty, dedicated to public health.

The Lisbon Treaty (as well as the Amsterdam Treaty) has enhanced the importance of health policy and highlighted its cross-cutting character in the European Union system, stating in Article 168 TFEU that “a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”.

It follows from paragraph 7 of this provision that it is the Member States that have exclusive competence for the setting of national health policies, including the organization and delivery of health services to be exercised, however, in compliance with EU law²⁹. The paragraph under discussion has been considered as a sort of “guarantee clause”³⁰ expressing the willingness of States to maintain control of the health sector.

Therefore, when it comes to health, the European Union has limited powers: its action “complements national policies” and “includes the fight against the major scourges by promoting research into their causes, their spread and their prevention, (...) as well as monitoring, alerting and combating serious cross-border threats to health”. It follows that, on the one hand, there is the action of the European Union, which is aimed at ensuring a high level of human protection and, on the other hand, there is the fundamental implementing

²⁷ Decision of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health, repealing Decision No 2119/98/EC, Decision No 1082/2013/EU, OJ L 293/1, 5 November 2013.

²⁸ Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community [1998] OJ L268/1.

²⁹ See also *inter alia* Judgment of 7 February 1984, case 238/82 Duphar BV and Others v. Netherlands State, pp. 540 ff., para 16; Judgment of 23 October 2003, case 56/01, Inizan v. Caisse, p. I-12433, para. 17.

³⁰ Francesco Bestagno, “La tutela della salute tra competenze dell’Unione Europea e degli Stati Membri”, in Laura Pineschi (ed), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari*, Naples, Editoriale Scientifica, 2017, p. 122.

legislative activity of the Member States, which act in accordance with their constitutional principles and the law of the European Union.

The limited action of the European Union is coordinated by the European Commission, which acts in the general interest of the Union, and its measures must also be approved by the Council representing the national governments. This is because the European Union is not a body with general aims and powers. It can only act in those areas where its action is covered by the Treaties and only for the objectives that the Treaties themselves indicate. The Member States have not transferred to the European Union powers to combat serious threats to health of a cross-border nature and more generally in the field of health, jealously guarding this power for themselves. In essence, individual States play a key, decisive and paramount role in the health sector. The European Union, on the other hand, has to intervene to coordinate national action and promote the exchange of knowledge, skills and materials necessary for the common benefit of the Member States, but it cannot adopt initiatives for regulatory harmonization, leading in the latter case to the absence of common and uniform responses to health emergencies.

In addition, the European Union is to encourage medical-scientific research, in particular in the fight against the great diseases and encourage research on their causes, their propagation and their prevention, within the principles of health information and education.

It should be noted that the provision contained in Article 168 TFEU is found in several rules of general scope, such as the social clause included by the Lisbon Treaty in Article 9 TFEU, which specifies the social objectives that the European Union must pursue in defining its policies and actions and the rule on “health protection” contained in the Charter of Fundamental Rights in Article 35. From this provision it emerges that health protection is a real social right articulated in the public provision of care to the sick and in health prevention, also in terms of healthiness of the environment and safety of working conditions.

The Charter ensures, in the section on “Solidarity”, the right of every person “to access health prevention and to obtain medical care”, under the conditions established by national laws and practices with the guarantee of a “high level of human health protection”. Therefore, the article, which is not very innovative compared to Article 168 TFEU, first establishes the right of access to medical care and the right to access to prevention and then refers to national legislation and practice with regard to the relevant modalities.

Moreover, it has been highlighted that the health protection provided by Article 35 has a rather limited effectiveness, since it leaves to national laws and practices the choice of whether and to what extent to guarantee the right,

thereby leaving the States free from any constraint³¹.

Despite the revision of the Treaties over time and the adoption of the Nice Charter, which became binding with the Lisbon Treaty, a vague picture emerges from the provisions on cross-border healthcare on the social dimension of health within the European Union, which accentuates its inferior role in the field of social rights compared to that of the Member States³².

Even following the establishment and proclamation of the European Pillar of Social Rights (EPSR), which aims to bring together the rights and principles that are part of the *acquis communautaire*, sometimes enriching it, the situation has not changed³³. To remedy this situation, the efforts of the European Union should be aimed at strengthening social policies through common and uniform projects based on the principle of solidarity.

The Union can count on a diversified set of instruments implemented to combat the spread of epidemics. This has not led to the creation of a single legal framework but to a “patchwork”³⁴ of rules and legal instruments that pursue different purposes and objectives. However, this circumstance, as has been highlighted in the literature, can lead to a fragmentation of the European response with consequent repercussions on its effectiveness³⁵. Therefore, the consequence is that States may have differentiated protocols that make it more difficult to provide a unified, strong, decisive response to health emergencies. This is evidenced by the recent emergency caused by COVID-19. Initially, some States reacted with indifference, thinking that this health crisis would affect only a few and would not involve all EU states, acting in a piecemeal manner.

The European Union too initially reacted in a fragmented way and with diversified and uncoordinated interventions. European solidarity came late. The differentiated responses of the Member States of the European Union to the pandemic declared by the WHO have highlighted the inadequacy of national responses to globalized problems and the fact that the European Union is still a regional organization for economic integration linked to an intergovernmental cooperation model, still very far from a federal model.

³¹ Donatella Morana, “Diritto alle cure e mobilità sanitaria nell’Unione europea: un banco di prova per l’Europa sociale. Note introduttive”, in ID (ed), *L’assistenza sanitaria transfrontaliera. Verso un welfare state europeo?*, Naples, Edizioni Scientifiche Italiane, 2018, p. 13 ff.

³² Massimo Luciani, “Diritti sociali e integrazione”, in *Politica del diritto*, 3/2000, p. 378.

³³ Anna Papa, “La tutela multilivello della salute nello spazio europeo: opportunità o illusione?”, in *Federalismi.it*, special issue 2018/4, *La dimensione europea dei diritti sociali*, P. Bilancia (ed.), p. 80 ff.

³⁴ Mary Guy and Wolf Sauter, *The history and scope of EU health law and policy*, in “EU public health law and policy, communicable diseases”, in Tamara K. Hervey, Calum Alasdair Young and Louise E. Bishop, *Research handbook on EU Health law and Policy*, Cheltenham, UK - Northampton, MA, USA, Edward Elgar Publishing, 2017, p. 17-35.

³⁵ Federico Casolari, “Il contributo delle organizzazioni internazionali e regionali alla gestione delle crisi sanitarie: il caso dell’epidemia di Ebola”, in *supra* note 15, p. 242.

There was also medical tension in Europe because no one had the necessary medical supplies and personal protective equipment. Witness, in particular, the Italian situation and specifically, the request of the leaders of the country of 26 February 2020 addressed to the Emergency Response Coordination Center to cope with the shortage of medical personnel, protective equipment and ventilators. EU Member States started to send supplies only in mid-March, while China was already providing medical experts, supplies and equipment.

The European Commission has played an important role by doing a great deal within its limited powers. Initially, on the basis of the European Civil Protection Mechanism, the Commission decided on 19 March to create a strategic stock (rescEU), i.e. a shared European reserve of emergency medical equipment such as ventilators, protective masks and laboratory supplies for the EU countries that need them. This stockpile is 100% funded by the Commission and managed by an Emergency Response Coordination Center (ERCC), which manages the distribution of equipment to ensure that it is sent where it is most needed. Germany and Romania were the first Member States to host the rescEU reserve. The creation of the rescEU equipment sharing European programme is, without doubt, a first, albeit not yet sufficient step to sever the dependency link with third countries, which remain, to date, the main exporters of essential products.

As a matter of fact, the Member States of the European Union depend too much on third countries for a number of products, for example India and China with regard to the production of vaccines, masks, ventilators and protective suits. The EU is highly reliant on these countries and was already dependent on them at the time of SARS in 2003-2004. This should undoubtedly make us consider an industrial strategy to avoid the same difficulties in the future and reduce this dependence. Indeed, in order to deal with this dependence and the shortage of essential products, a diversification of the supply sources and a production aimed at the creation of a strategic reserve of essential products to be ensured throughout Europe in an equal manner in order to meet every need would be desirable.

In order to address overburdened hospitals, the Commission has also published a set of practical guidelines for Member States to support and encourage cross-border cooperation between national, regional and local authorities in the field of healthcare³⁶. Said cross-border cooperation is envisaged in order to alleviate the pressure on overburdened hospitals by transferring coronavirus patients seeking treatment to other Member States where beds are available³⁷.

³⁶ Healthcare is understood as having the same meaning as in Directive 2011/24/EU on cross-border healthcare provided in a Member State other than the Member State of affiliation, and does not exclusively concern healthcare provided in a neighbouring Member State.

³⁷ Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis (2020/C 111 I/01).

In particular, the Guidelines are concerned with coordinating the demand and supply of beds, emergency cross-border transport, reimbursement of medical expenses and practical arrangements for patient transfer.

The starting point is the notification by the Member State concerned to the Early Warning and Response System (EWRS) while Member States use the very EWRS to make themselves available. For its part, the Commission, through the ERCC, will have to coordinate and co-finance medical transport.

As regards the financial aspect, although the Guidelines reaffirm that healthcare remains the responsibility of the Member State of affiliation, they add in closing that the Union shall provide support through the Solidarity Fund and that healthcare expenditure is “eligible expenditure” under the Structural Funds while other instruments are being examined by the institutions. They will serve, in particular, for the “transportation of patients in need to cross-border hospitals which can offer free capacity, exchange of medical professionals, hosting foreign patients or other type of mutual support and deployment of temporary health care facilities”³⁸. The European Commission has also proposed the activation of the safeguard clause of the Stability Pact and lastly, on 27 May 2020, it presented “a historic and one-off proposal”³⁹ for a “Next Generation EU” post-pandemic recovery plan to help the most affected Member States to recover from the COVID-19 crisis, but also to improve the European Union as a whole.

4. Recovery Fund: Will it be a real turning point in the way the European Union deals with health?

Several important initiatives have been planned to cope with the huge economic and social damage caused by the COVID 19 pandemic in Europe. Think of the quantitative easing of the European Central Bank, an *ad-hoc* credit line, that is the “Pandemic Crisis Support” (PCS), the Sure European redundancy fund⁴⁰ and the possibility to use the European Stability Mechanism (ESM) under minimum conditions for direct and indirect health care costs.

Finally, on 21 July 2020, the European Council reached an agreement,

³⁸ *Ibidem*, par. 9.

³⁹ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, Europe’s moment: Repair and Prepare for the Next Generation {SWD(2020)98final}.

⁴⁰ The “Support to Mitigate Unemployment Risks in an Emergency” (SURE), established on 19 May 2020, is a temporary instrument proposed by the European Commission in the context of the EU strategy for a coordinated economic response to mitigate unemployment risks. See Council Regulation (EU) 2020/672 of 19 May 2020 on “the establishment of a European instrument for temporary support to mitigate unemployment risks in an emergency (SURE) following the Covid-19 outbreak”.

after 92 hours of negotiations, on the common response to the biggest economic recession in the history of the European Union, represented by “Next Generation EU”, which was celebrated as a historic achievement and was considered as a sort of “Marshall Plan for Europe”. The six-monthly budget proposal updated by the EU amounts to 1 trillion euro, and the goal of the 750-billion-euro recovery plan is “to drive and build a more sustainable, resilient and equitable Europe”. This figure is unprecedented in the history of the European Union. It is no coincidence that the Commission calls the whole initiative “Next Generation EU”. The “Next Generation EU” plan is one of the measures envisaged by European institutions, and its peculiarity would lie in the issuance of bonds on the financial markets on behalf of the European Union, to raise funds to be disbursed mainly through grants, but also loans. This would involve a significant increase in the common budget up to 2% of the gross national income of the European Union and the introduction of own resources of the European Union, in the form of a carbon tax, web tax, plastic tax or a tax on financial transitions.

The funds raised by “Next Generation EU” will be combined into three pillars. The first pillar concerns the support to Member States for investments and reforms that will be monitored by the Commission through the European Semester or through the presentation of appropriate “National Recovery Plans”, which will give an account of how the money is spent and the reforms are implemented. This will be done mainly through the “Recovery and Resilience Facility”, which can count on about 560 billion euros to be distributed both through grants and loans.

The second pillar has the objective of relaunching the economy of the European Union by stimulating private investment and directing it towards companies in difficulty in the countries most affected.

The third pillar, “EU4Health Programme”, will instead invest in building capacity and preparedness for major cross-border health threats and the purchase of medicines and medical instruments. The intention of the Commission is a long-term objective to ensure efficient and resilient public health systems, in particular by investing in disease prevention and surveillance and improving access to healthcare, diagnosis and treatment.

Therefore, with “Next Generation EU”, the Commission is setting itself ambitious objectives also in the health sector. In particular, in order to be prepared for future health crises, it intends to strengthen the European Medicines Agency, monitoring the production and supply of essential medicines in the European Union to avoid future shortages; to give the European Center for Disease Prevention and Control (ECDC) – based in Stockholm, which provides national authorities with real-time statistical data, studies, risk analysis and issues recommendations and guidelines – the task of coordinating surveillance,

preparedness and response to health crises; to strengthen the EU health regulatory framework and the use of joint procurement for health supplies; to promote the exchange of health data and support research in full compliance with the protection of personal data. An important role will be attributed to research and innovation, where a real strategy at European level is still lacking. Research and innovation are considered essential to increase knowledge of diseases or treatments and vaccines. The development of a vaccine is a long and complex process. With regard to vaccination policies and programmes, although each State is responsible within its national territory, the European Union is called upon to promote and complement national vaccination policies. The Commission has presented a European strategy to accelerate the development, production and distribution of vaccines against Covid-19⁴¹. In addition, the Commission also wants to create a new pharmaceutical strategy. The agreement reached in the European Council clearly shows a Europe that is present and attentive to the needs and difficulties of all Member States. Given the exceptional nature of the current crisis and the scale of its financial and economic effects, financial support in a spirit of solidarity between Member States is justified.

Unfortunately, this crisis was unpredictable and unexpected, although it was not the first time that the European Union was faced with a pandemic emergency. In retrospect, it becomes clear that the European Union, despite previous crises, has not equipped itself over time to deal with new epidemic threats. Unfortunately, viruses have existed for hundreds or thousands of years, and for this reason the European Union should have prepared itself. This unfortunate situation has shown that the fight against global challenges must be faced by the European Union as a whole, because individual States alone are unable to cope. The need for efforts on the part of the European Union and observance of the principle of solidarity that inspired the founding fathers are now more topical than ever. Indeed, the States have realized that now more than ever, economic and financial solidarity is needed to get out of the crisis.

The Covid-19 pandemic, which is putting the European Union to the test, does not mark the end of the European project, but enables us to draw lessons from the events we are experiencing, for us to see it as an opportunity to rethink the structure of European governance and relaunch a new model of the European Union. It is therefore a moment of truth for Europe! This unfortunate situation is in fact showing the need to have a strong political project and not one with a somewhat reduced vision of the market as was the case in the beginning.

⁴¹ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL AND THE EUROPEAN INVESTMENT BANK EU Strategy for COVID-19 vaccines. Brussels, 17 June 2020 COM (2020) 245 final.

5. Conclusion

Therefore, the health emergency has led to the rediscovery of the value of the right to health and the crucial role of healthcare and its operators, brutally highlighting the need, until now hidden from the eyes of a distracted public, for intensive care and infectious disease wards. All this is leading to disruptive and innovative social and healthcare changes, compared to those recorded so far at a national, European and international level, accelerating the processes of change that were already underway.

The current crisis has underlined the need for coordination and response not only at an international level, but also at a European and national level. In today's globalized, interconnected world, it is impossible to separate the individual actions of States or the European Union from international politics.

However, the serious and extraordinary situation generated by COVID-19 has instead shown the world the need to have a World Health Organization – which has unfortunately demonstrated serious limitations during the crisis – that is reformed and able to ensure adequate cooperation.

As a matter of fact, the temporary measures of 30 January 2020 adopted by the Director-General of the WHO, but also the numerous recommendations and guidelines of the WHO, have proved ineffective and inadequate to ensure the coordination of States in the fight against the pandemic. Indeed, while COVID-19 was impacting the entire globe, each government worked independently to keep their communities safe and to enable an effective response to the pandemic. This situation highlighted the need for increased coordination and information sharing beyond national boundaries to develop and implement common strategies to protect human health. Human health depends not only to accessible health care but also on access to accurate and reliable information about the nature of the threat represented by COVID-19. Both are closely related. There is no doubt that the access to accurate, prompt and updated information in times of crises helps people make safe choices for themselves, their families and the whole community. The right to information is recognized under international law as fundamental human right. Consequently, States have an obligation to respect this fundamental right by providing truthful information on pandemic situations and fighting disinformation.

Moreover, the absence of coordination and shared actions among States is supported by the fact that many governments, by applying strong unilateralism, have taken additional measures restricting the personal freedoms of their citizens to deal with the unprecedented situation and the failings of their national systems.

In fact, article 43 of the 2005 Regulation enables one to go beyond the actions recommended by the WHO, providing for the possibility to apply

measures in accordance with the respective national legislation, especially when this choice is in favour of more effective measures than the obligations provided for at international level, but only under certain conditions. However, this has led States to give an equivocal response to this health emergency. Indeed, it was the States that were responsible for identifying how to prevent and control the virus within their jurisdiction, and their response was slow and fragmented. Therefore, in this case, the IHR does not seem to have ensured a uniformity of standards in this field. When faced with a complex crisis, States have put aside the bona fide multilateral cooperation that would have been necessary to deal with a shared problem. The members of the international community have exhibited unilateralism.

However, in the face of an extraordinary situation, an unprecedented response is needed. A strong multilateralism is fundamental because no State can succeed on its own. The emergency situation of recent months has shown that States must pursue more strongly the development of common actions in similar situations. To achieve this goal, however, the WHO must overcome the structural fragilities inherent in its Constitution and regulations that emerged during the COVID-19 emergency. These fragilities were exemplified by the WHO's inability to ensure compliance by States with its recommendations, by the weakness of the WHO's approach, which is based more on the rule of experts than on the rule of law, by the absence of the IHR sanctioning system, which does not guarantee the effectiveness of the obligations undertaken by States and by the lack of an adequate dispute settlement mechanism that facilitates peaceful resolution.

Therefore, the unprecedented crisis due to the sudden escalation of the pandemic should lead to a rethinking of the WHO's structure, which has shown more cons than pros in this situation.

On the European level, however, there has been a strong, albeit not immediate, response in the health context, probably not, but in other situations caused by the pandemic there have been many actions. For instance, in relation to the right of passengers to refund the payment of their unused tickets and many other things, related to issues for which the EU has powers.

Indeed, the lack of solidarity shown by the States in the first weeks of the spread of the virus and the difficulties that the European Union has faced have put it to the test, as it lacks or almost lacks competence in health matters. The fragmentation of the European response to the COVID-19 pandemic has immediately highlighted the importance and urgent need for solidarity among Member States.

This crisis was unpredictable and unexpected, although it was not the first time that the European Union was faced with such an emergency. In retrospect, it becomes clear that the European Union, despite previous crises, has not

equipped itself over time to deal with new cross-border threats. Unfortunately, viruses have existed for hundreds or thousands of years, and for this reason the European Union should have prepared itself.

It is clear, therefore, that the fight against global challenges should be addressed by the European Union as a whole. The Covid-19 pandemic is proving to be an opportunity for the European Union to rethink the structure of European governance and to relaunch a new model of the European Union and not to make the mistakes of the past! The “Next Generation EU” post-pandemic recovery plan to help the Member States most affected to recover from the COVID-19 crisis, but also to improve the European Union as a whole and the health sector, is a good starting point and an unprecedented response that, were it to become a reality, could represent a step forward in the process of European integration. The prerequisites are there, because the agreement reached in the European Council clearly shows a Europe that is present and attentive to the needs and difficulties of all Member States. Given the exceptional nature of the current crisis and the extent of its financial and economic effects, financial support in a spirit of solidarity between the Member States is justified. Solidarity, which is a fundamental value of the European Union and its Member States and is at the basis of the principle of loyal cooperation, is recently gaining visibility, and its importance is being rediscovered again. The future must be looked at through the eyes of solidarity and not through the filter of selfishness.

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